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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/594,920	09/29/2006	Kazuwa Nakao	1254-0328PUS1	5293

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EXAMINER	
HOWARD, ZACHARY C	
ART UNIT	**PAPER NUMBER**
1646	

NOTIFICATION DATE	DELIVERY MODE
02/08/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

mailroom@bskb.com

Office Action Summary	Application No.	Applicant(s)	
	10/594,920	NAKAO ET AL.	
	Examiner	Art Unit	
	Zachary C. Howard	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-51* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Application, Amendments and/or Claims

The preliminary amendments of 9/29/06 and 3/16/07 have been entered in full. Claims 9, 34, 38 and 51 are amended.

Claims 1-51 are pending in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-19 and 40-43, drawn to drawn to an agent comprising a guanyl cyclase B (GC-B) activator.

Group II, claim(s) 20-31, drawn to a method for inhibiting arthritis or promoting the growth of articular chondrocyte by activating GC-B.

Group III, claim 32-39, drawn to a method of screening for an agent that promotes articular chondrocyte growth by assaying GC-B activity.

Group IV, claims 44-50, drawn to an "activation promoter" comprising a nonsteroidal activator.

Group V, claim 51, drawn to a method for activating a GC-B activator by using a nonsteroidal activator.

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking groups I-V appears to be that they all relate to a product encompassed by the claims of Group I; specifically, an agent comprising a

guanyl cyclase B (GC-B) activator. The specification and the claims teach that C-type natriuretic peptide (CNP) is a GC-B activator, including both the 22 and 53 amino acid forms (e.g., see claim 9). The recitations of "therapeutic or prophylactic" and "for arthritis" in independent claim 1 are interpreted as an intended use and do not distinguish the claimed product from a product taught by the prior art. Thus, the claims of Group I encompasses agents comprising a C-type natriuretic peptide.

The prior art teaches an agent comprising a C-type natriuretic peptide. Specifically, Tanaka et al, U.S. Patent No. 6,034,231, published March 7th, 2000, teaches human prepro CNP (126 amino acids), CNP-22 (22 amino acids) and CNP-53 (53 amino acids). See entire document; in particular, column 4, lines 30-46. Tanaka further teaches that CNP-22 and CNP-53 are derived from prepro CNP (col 4, line 46). Therefore, prepro CNP is an agent comprising CNP-22 and CNP-53, and is thus is a product encompassed by the claims of Group I.

Therefore, the technical feature linking the inventions of Groups I-V does not constitute a special technical feature as defined by PCT rule 13.2, as it does not define a contribution over the prior art.

Elections of species

In addition to the above restriction requirement, three elections of species are required as follows.

(1) This application contains claims directed to more than one species of GC-B activator. The species are as follows: CNP-22 and CNP-53

The claims correspond to the species listed above in the following manner:

1. Claims 1-8, 13, 14, 19, 20, 25, 26, 32-44 and 49-51 are generic.

2. Claims 9, 15, 21, 27, 31 and 45 are generic to any CNP peptide.

3. Claims 10-12, 16-18, 22-24, 28-30 and 46-48 recite each species as part of a Markush-type group.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species

do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each CNP peptide is a structurally discrete peptide with a different sequence. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(2) This application contains claims directed to more than one species of arthritis: (a) osteoarthritis that is degenerative gonarthrosis; (b) osteoarthritis that is degenerative coxarthrosis; (c) osteoarthritis that is temporomandibular arthrosis; or (d) rheumatoid arthritis.

The claims correspond to the species listed above in the following manner:

1. Claims 1, 9-39 and 44-51 are generic.
2. Claims 2, 3, 4, 8, 40 and 41 correspond to species (a).
3. Claims 2, 3, 5, 8, 40 and 41 correspond to species (b).
4. Claims 2, 3, 6, 8, 40 and 41 correspond to species (c).
5. Claims 7, 42 and 43 correspond to species (d).

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each type of arthritis has a different etiology and affects different tissues. Lack of unity is shown because these diseases lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

(3) This application contains claims directed to more than one species of nonsteroidal compound (anti-inflammatory drug or activator): indomethacin, ibuprofen, piroxicam, salicyclic acid, diclofenac, ketoprofen and naproxen.

The claims correspond to the species listed above in the following manner:

1. Claims 1-48 and 51 are generic to a nonsteroidal inflammatory compound.

2. Claim 49 is generic to a cyclooxygenase inhibitor (includes each species).

3. Claim 50 recites each species as part of a Markush-type group.

These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1. The species do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons: each nonsteroidal compound is a discrete chemical compound that is different from each of the other compounds and each compound can be used independently of the other. Lack of unity is shown because these treatments lack a common utility which is based upon a common structural feature which has been identified as the basis for that common utility.

Applicant is required, in reply to this action, to elect a single species of (1) CNP; (2) arthritis and (3) nonsteroidal compound to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Rejoinder

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder.

All claims directed to a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Zachary C. Howard whose telephone number is 571-272-2877. The examiner can normally be reached on M-F 9:30 AM - 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on 571-272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

zch

/Elizabeth C. Kemmerer/
Primary Examiner, Art Unit 1646